

11-20-00

Attorney Docket No. 5877-0011.30

H

11/17/00
USPTO
11/17/00

09/15 U.S. PRO
09/15 U.S. PRO
11/17/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Certification under 37 CFR §1.10 (if applicable)

EL 530 372 993 US

Express Mail Label Number

November 17, 2000

Date of Deposit

I hereby certify that this Transmittal Letter, enclosed application and any other documents referred to as enclosed herein, are being deposited in an envelope with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Deborah Brockmeyer
(Print Name of Person Mailing Application)

Deborah Brockmeyer
(Signature of Person Mailing Application)

Transmittal of Utility Patent Application
for Filing Under 37 CFR §1.53(b)

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is a utility patent application by inventors: Patrick Rivelli, Jr. entitled:

NEUROVASCULAR STENT AND METHOD

1. Enclosed are:

- This Transmittal letter.
- One stamped, self-addressed postcard for PTO date stamp.
- Certificate of Express Mail.
- One utility patent application containing text pages 1-17 and 7 Sheets of drawings.
- Declaration of inventorship (unsigned)
- * Assignment(s) for recordation with transmittal sheet.
- Executed Power of Attorney by Assignee
- Sequence listing printout, diskette, and matching declaration.

2. U.S. Priority

- This application claims priority of U.S. Provisional Patent Application Serial No. 60/241,101 filed on October 16, 2000, expressly incorporated in its entirety herein by reference.
- A petition for extension of time has been filed in the parent to extend the pendency of the parent to * (copy enclosed).
- Conditional Petition for Extension of Time: An Extension of Time is requested to provide for timely filing if required to establish copendency with the parent after all papers filed herewith have been considered.

3. Foreign Priority

- Priority of Application No. * filed in * on * is claimed under 35 USC §119.
- A certified copy of this priority document is enclosed.

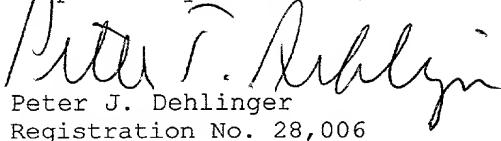
4. Fees

The filing fee has been calculated as shown below:

| For: | (Col. 1) No. Filed | (Col. 2) No. Extra | Small Entity | | or | Other Than a Small Entity | |
|---|-----------------------|-----------------------|--------------|----------|----|---------------------------|----------|
| | | | Rate | Fee | | Rate | Fee |
| Basic Fee | | | | \$355.00 | or | | \$710.00 |
| Total Claims | 17 - 20 | 0 | 0 x \$ 9 = | \$ 00.00 | or | x \$ 18 = | \$ |
| Independent Claims | 3 - 3 | 0 | 0 x \$40 = | \$ 00.00 | or | x \$ 80 = | \$ |
| <input type="checkbox"/> Multiple Dependent Claim Presented | | | + \$135 = | \$ | or | + \$270 = | \$ |
| * If the difference in Col. 1 is less than zero, enter "0" in Col. 2. | | | TOTAL | \$355.00 | Or | TOTAL | \$ |

- Applicant claims small entity status. See 37 CFR §1.27
- A check for \$* is enclosed to cover the Filing Fee.
- Please charge Deposit Account 04-0531 in the amount of \$*.
- The Commissioner is hereby authorized to charge fees under 37 CFR §1.16 and §1.17 which may be required, or credit any overpayment to Deposit Account 04-0531.
- Filing fee to be submitted in response to anticipated receipt of Notice to File Missing Parts of Application. DO NOT CHARGE DEPOSIT ACCOUNT.**

Respectfully submitted,


Peter J. Dehlinger
Registration No. 28,006

Date: 11-17-2000

Correspondence Address:

Customer No. 22918
Phone: 650-324-0880

Transmittal of Utility Patent Application for Filing

Certification Under 37 C.F.R. §1.10 (if applicable)

EL 530 372 993 US
"Express Mail" Label NumberNovember 17, 2000
Date of Deposit

I hereby certify that this application, and any other documents referred to as enclosed herein are being deposited in an envelope with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

Deborah Brockmeyer

(Print Name of Person Mailing Application)



(Signature of Person Mailing Application)

NEUROVASCULAR STENT AND METHOD

This application claims priority of U.S. Provisional Patent Application

5 Serial No. 60/241,101 filed on October 16, 2000, expressly incorporated in its entirety herein by reference.

Field of the Invention

10 The present invention relates to a vascular endoprosthesis, such as a stent, for placement in an area of a body lumen that has been weakened by damage or disease such as by aneurysm, and in particular, to a stent adapted for placement at a neurovascular site, and to a method of using the stent in treating a neurovascular aneurysm.

15 Background of the Invention

Rupture of non-occlusive cerebrovascular lesions, such as intracranial saccular aneurysms or arterio-venous fistulae, is a major cause of stroke. Rupture of an aneurysm causes subarachnoid hemorrhage in which blood from a ruptured vessel spreads over the surface of the brain. About 2.5% of the 20 United States population (4 million Americans) have an unruptured aneurysm. About 100,000 of these people suffer a subarachnoid hemorrhage each year. The disease is devastating, often affecting healthy people in their 40's and 50's, with about half of the rupture victims succumbing within a month, and with half of

the survivors becoming seriously disabled as a result of the initial hemorrhage or of a delayed complication.

Neurovascular arteries are generally quite small, having diameters ranging from 2.0 to 4.0 mm in the Circle of Willis, 2.5 to 5.5 mm in the cavernous segment of the internal carotid artery, 1.5 to 3.0 mm in vessels of the distal anterior circulation, and 2.0 to 4.0 mm in the posterior circulation. The incidence of aneurysm varies with the location, with 55% occurring in the Circle of Willis, 30% in the internal carotid, 10% in the distal anterior circulation, and 5% in the posterior circulation.

Screening for these lesions and preventing rupture will lead to better clinical outcomes and lower costs. Non-invasive treatments for ruptured and unruptured lesions are preferred over surgical interventions due to lower costs, lower mortality and morbidity, and patient preference.

One possible treatment for neurovascular aneurysms and other small-vessel abnormalities involves placement of a stent at the site of weakened or damaged vessels. Such a treatment, however, involves several formidable challenges. First, assuming the stent is placed at the target site via a small-diameter catheter, the stent must be flexible enough to allow movement of the catheter along a typically tortuous vascular path, which may involve a number of sharp turns or bends in and through small-diameter vessels, *i.e.*, vessels having diameters in the 2-8 mm range. Second, when the stent is released, it must be capable of expanding from the inner-lumen diameter of the catheter to a diameter somewhat greater than that of the vessel at the target site, requiring an expansion ratio of at least twofold. Third, the stent must provide adequate structural support at the target site to maintain the vessel in a slightly expanded-diameter state. In particular, the stent design should minimize the risk of metal fatigue as the stent is placed between its expanded and compressed forms. Fourth, the stent must provide a low profile and a surface that minimizes the formation of blood thrombi. Finally, the stent should provide an open-network skeleton that allows for delivery of additional agents, *e.g.*, vaso-occlusive coils, through the stent into the underlying aneurysm cavity.

Although a variety of intravascular stents have been proposed heretofore, for example, in U.S. Patent Nos. 4,512,338, 4,503,569, 4,553,545, 4,795,485, 4,820,298, 5,067,957, 5,551,954, 5,562,641, and 5,824,053, none of these structures adequately meets the several requirements outlined above. In 5 particular, the problem of providing a stent skeletal structure that has a contracted state diameter of 0.5-2 mm, is highly flexible in a contracted state, has a high expansion ratio on delivery from a catheter, and resists metal fatigue on expanding and contracting, has not been adequately solved heretofore.

It would therefore be valuable to provide an intravascular stent, particular 10 one for use in treating neurovascular aneurysms and other vascular abnormalities, that provides the advantages and features mentioned above.

Summary of the Invention

The invention includes, in one aspect, a stent designed for catheter 15 delivery to a target neurovascular site via a tortuous path in a contracted state, and deployment at the target site in an expanded state. The stent includes a plurality of expandable tubular members, where each member is composed of a continuous wire element forming a plurality of wave segments, and each segment contains a pair of opposite looped peaks and has a wave shape such 20 that the distance between adjacent sides of a wave in the stent's expanded state, on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween. Adjacent tubular members are connected by axial connectors, preferably joining adjacent peaks of adjacent members, and preferably spaced from one another by intervening, unconnected 25 confronting peaks. Radial expansion of the stent from a contracted to expanded state is accommodated by movement of adjacent wave-segment peaks away from one another, without significant change in the axial dimension of the stent.

In a preferred embodiment, the wire elements are formed of a NiTi shape 30 memory alloy, and radial expansion is achieved by releasing the stent from such catheter. The stent of this embodiment may have a stress-induced martensite phase at body temperature, and/or an austenite phase transition temperature below body temperature.

Also in a preferred embodiment, the stent has a diameter, in its contracted state of between 0.5-2 mm, more preferably 0.71 mm to 1.65 mm, and an expansion ration of between 2 and 9, typically 3 and 6.

In another aspect, the invention includes a system for treating an 5 aneurysm or other vascular abnormality in a neurovascular target vessel having an inner diameter less than about 8 mm and accessible via a tortuous vascular path. The system includes a guide wire that can be deployed at the target site, a catheter having a lumen inner diameter of 0.5 to 2 mm, and the above stent carried in its contracted state within the catheter's distal end region. The 10 catheter and stent carried therein are adapted to be moved axially along the guide wire, for placing the catheter at the target site. Also included is a pusher wire movable through the catheter, for forcing the stent out of the catheter into the vascular site, where stent radial expansion is effective to lodge the stent at the target site. The pusher wire may be equipped with a distal-end stabilizer that 15 is engageable with the stent when forcing the same from the catheter. Preferred stent features are given above.

In still another aspect, the invention includes a method of treating an 20 aneurysm or other vascular abnormality in a neurovascular target vessel having an inner diameter less than about 8 mm and accessible via a tortuous vascular path. The method includes navigating a guide wire to the target site, and moving over the guide wire, a catheter having a lumen inner diameter of 0.5 to 2 mm, and the above stent carried in its contracted state within the catheter's distal end region, until the catheter distal end is located at the target site. The guide wire is then replaced with a pusher wire, which is used to advance the stent out of the 25 catheter into the vascular site, where stent radial expansion is effective to lodge the stent at the target site.

These and other objects and features of the invention will become more fully apparent when the following detailed description of the invention is read in conjunction with the accompanying drawings.

Brief Description of the Drawings

Fig. 1 is a side view of portions of a pair of connected tubular members forming the stent of the invention, and shown in a contracted state;

Fig. 2 shows the same tubular members in an expanded state;

5 Fig. 3 shows a portion of a stent constructed according to the invention, in a contracted state;

Fig. 4 shows the same portion of the stent, but in an expanded state;

Figs. 5A and 5B illustrate the change in distance between adjacent sides of a wave segment in a tubular member, on proceeding from a lower wave peak 10 to the opposite (upper) side of member (5A), and a plot this distance as a function of the peak-to-peak distance, showing the inflection point in the distance plot;

Figs. 6A and 6B show various components of the system of the invention, in a stent-delivery method, and at two stages of stent delivery;

15 Figs. 7A and 7B are expanded views of distal end portions of the system, of the invention, shown in relation to a vascular target site, just prior to release at the target site (7A) and after deployment at the site and stent expansion in the target vessel.

20 Detailed Description of the Invention

Figs. 1 and 2 show a portion of a stent 10 constructed in accordance with the invention, in the stent's contracted and expanded states, respectively. The stent includes a plurality of expandable tubular members, such as tubular members 12, 14. In actual construction, the stent may include many such members, e.g., 2-20, collectively forming an elongate cylindrical tube.

25 Each member of the stent is formed of a continuous wire element, such as wire element 16 in member 12, forming a plurality of wave segments, such as wave segments 18, 20 in member 14, whose shape and expansion characteristics will be described further below with respect to Figs. 3-5. The 30 wave segments have opposite looped peaks, such as looped peaks 22, 24 in wave segment 18.

Adjacent tubular members are connected one to another by axial connectors, such as axial connector 26 joining members 14, 16, and axial connector 28 joining tubular member 12 to a third member (not shown). As seen, the axial connectors connect confronting peaks in adjacent members,

5 although connections to other parts of the wave segments is contemplated. In a typical stent, the connectors are spaced from one another by at least one, and preferably three or four unconnected confronting peaks. That is, a majority of the confronting peaks are unconnected, providing greater stent flexibility in bending away from the stent long axis. Although the connectors shown here are

10 simple linear connectors, the connectors may assume more complicated configurations, such as curved or zig-zag shapes which may themselves stretch to accommodate off-axis bending of the stent, providing greater flexibility.

Preferably, the stent has a contracted-state diameter (Fig. 1) of between 0.5-2 mm, more preferably 0.71 to 1.65 mm, and a length of between about 0.5-15 4 cm, composed of 2-20 tubular members, each about 0.25 to 1.0 mm in length. The axial connectors have a length typically of 3-20% that of the tubular members.

Each tubular member is composed of between 5-25 wave segments, defined as repeating segments of the associated wire elements, as described 20 below with respect to Figs. 3-5. In its expanded state, shown in Fig. 2, the stent diameter is at least twice and up to 8-9 times that of the stent in its contracted state. Thus, a stent with a contracted diameter of between 0.7 to 1.5 mm may expand radially to a selected expanded state of between 2-8 mm or more.

The relationship between the shape of the wave segments in the tubular 25 methods and the mode of radial expansion of the stent is illustrated particularly in Figs. 3 and 4, which show portions of the tubular members as they would appear if laid out in a plane. In particular, the figures show portions of tubular members 12, 14, each formed of a continuous wire element, such as wire element 18 forming member 14. Each wire element, in turn, is formed of a 30 series of repeating-unit wave segments, such as wave segments 18, 20, where the "end" of one segment is the "beginning" of the next segment.

The "end/beginning" point of the wave segments, which occurs at the same phase point in each wave, is arbitrary, and for purposes of illustration is indicated at a point, such as indicated at 30, 32, 34, which is near the top of the loop in the upper looped peak of each wave segment. Thus, wave segment 18 5 is defined as the portion of the wire element between points 30,32, and segment 20, as the portion of the element between points 32, 34.

In the stent's contracted state, the wave segments are compressed closely together, as seen in Fig. 3, where adjacent looped peaks are in contact with one another or nearly in contact, and the looped peaks are squeezed 10 together. According to an important feature of the invention, the wave segments forming the wire element accommodate movement of the opposite arms of a wave segment, such as opposite arms 36, 38 in segment 18, away from one another, with relatively larger movement occurring in the center portion of the wave segment, *i.e.*, the portion between opposite looped peaks.

15 This feature is illustrated particularly in Fig. 5A, which shows three adjacent wave segments, including segment 18 in its expanded (or expanding) form. Distances between opposite sides 36, 38 of wave segment, such as distances 40, 42, 44, are shown for a number of points between looped peak 46 in segment 18 and opposite looped peaks 48 in segment 18 and 50 in adjacent 20 segment 20. In the plot shown in Fig. 5B, the x-axis represents the distance from a peak in a wave segment to the opposite peak of the wave segment, with the ordinates 40, 42, 44 in Fig. 5A shown. The distance along the y-axis represents the distance between opposite sides of the wave segment. As seen, 25 the plot shows a relatively small slope ($\Delta x/\Delta y$) in the wave regions adjacent the peaks and the greatest slope in the center region of the segment between the looped peaks. The point of greatest slope, corresponding roughly to midpoint 42 between the peaks, is an inflection point in the plot, as the slope of the plot increases between points 40 and 42, then begins to decrease between points 42 and 44.

30 The characteristics of the wire-element shape provide several important advantages in a stent intended for use in a small-diameter site. First, the stent can be forced into a highly compressed or contracted state, (Figs. 1 and 3) with

relatively little bending or stress in the peak regions. This contrasts with a saw-tooth wave, where much of the compression stress is concentrated at the peak points, and also with a regular sin wave that lacks the ability to be compressed tightly due to its relatively wide peak loops. Similarly, the stress on axially 5 connected wire-element peaks that can occur when the stent is bent away from its long axis (during movement through a tortuous vascular path) is distributed over the loop region, rather than being concentrated at a point. Both aspects reduce the possibility of failure of the stent by metal fatigue.

At the same time, the element can undergo a severalfold radial expansion 10 by virtue of the ability to be close packed in a contracted state (unlike a sin wave), and still provide significant expansion between wave segments arms. This is in contrast to a sin-wave wire element in which compression at the peaks, and thus the number of wave segments that can be accommodated in the contracted state, is limited.

15 Finally, and as can be appreciated from Figs. 3 and 4, radial expansion of the stent produces little change in the overall length of the tubular members, preserving the overall stent length during deployment and expansion.

The stent may be formed by conventional stent construction methods 20 involving either initial formation of the individual tubular members, and subsequent attachment of one member to another by axial connectors, or by laser cutting a thin-walled tube to have the skeletal features making up the stent, as detailed below. In the former method, the wire element may be formed by shaping a wire segment and joining the wire ends to form the desired tubular member. In the latter case, the wire element is formed by cutting and removing 25 portions of a cylindrical tube.

The stent preferably exhibits a relatively high degree of biocompatibility 30 since it is implanted in the body. Where the stent is self-expanding, suitable stent materials include compressible, biocompatible polymers, ELGILOY (available from Carpenter Technology Corporation of Reading, PA) and PHYNOX (available from Metal Imphy of Imphy, France). Both of these metals are cobalt-based alloys which also include chromium, iron, nickel and molybdenum. Other materials for a self-expanding stent include 316 stainless

steel and MP35N alloy which are available from Carpenter Technology Corporation and Latrobe Steel Company of Latrobe, Pennsylvania, and superelastic Nitinol nickel-titanium alloy which is available from Shape Memory Applications of Santa Clara, Calif. Nitinol alloy contains about 45% titanium.

5 In one general embodiment, the stent is formed of a shape-memory alloy having a final austenite transition temperature of between about 25°C and 37°C. This feature allows the stent to be carried in the catheter in a martensitic state, and assume its preformed, austenitic shape when expelled from the catheter and exposed to the higher body temperature at the target site. In another 10 embodiment, the shape-memory alloy has a transition temperature M_d greater than 37°C, below which the alloy retains sufficient stress-induced martensitic property to allow placement of the stent at or above its A_f . In other words, this allows the stent to be carried in the catheter in a stress-induced martensitic (SIM) state, and recover its preformed, austenitic shape when released from the 15 constraints of the catheter, at a temperature that may be substantially above the final austenite temperature without significant plastic, or otherwise permanent deformation. In this embodiment, the final austenite temperature may be quite low, e.g., 4°C, or it may be room temperature or higher.

Nitinol cylindrical tubes having desired transition temperatures, as noted 20 above, can be prepared according to known methods. In an exemplary method of manufacture of the stent having these properties, a nitinol hypotube, e.g., 8 mil wall thickness, is subjected to centerless grinding to a wall thickness of 3 mil. The stent pattern is cut by a laser (e.g., as described by Madou in Fundamentals 25 of Microfabrication, CRC Press, 1997). Both inner and outer surfaces are polished to a mirror finish using electro-polish techniques (e.g., as described by Madou, 1997). A gold coat may be applied by ion beam assist, or by sputtering. Alternatively, or additionally, a radio-opaque marker may be affixed to the stent to improve radio-opacity.

During manufacture, the stent is formed at the expanded condition (Fig 2), 30 corresponding to the final deployed size (e.g., about 3-8 mm outer diameter), and heated to a temperature above the transition temperature. The stent is then subjected to thermoelastic martensitic transformation (e.g., as described in U.S.

Patent No. 5,190,546 incorporated by reference in its entirety herein) by cooling below the transition temperature range of the alloy and deformation to the contracted condition suitable for use within an intraluminal catheter. The transition temperature can be modified by varying the ratios of each metal in the 5 alloy and in one embodiment, is preferably is within the range between about 25°C to 45°C at which the stent expands. A more preferred transition temperature range is between about 25°C to 37°C. For example, the alloy can comprise 55% nickel, and 45% titanium which gives a transition temperature of about 32°C to 33°C, which is below body temperature but above room 10 temperature.

Nitinol cylindrical tubes having a martensite temperature M_D below which the alloy can assume a stress-induced martensitic condition while being stressed to the extent necessary to place or otherwise use the device, of greater than about 37°C, preferably greater than about 40°C, are also prepared according to 15 known methods, e.g., U.S. Pat. No. 4,505,767. For example an ideal alloy would act, at about 37°C, as a constant force spring over a strain range up to about 5% or more. This is a measurement of the degree to which an alloy, at a given temperature, can be strained in a purely austenitic state by the formation of stress-induced martensite without significant plastic deformation. In other words, 20 the strain caused by the application of a given stress at a given temperature is substantially recoverable. In practice, the maximum stress realized occurs sometime during the process of placing a nitinol device at a given temperature. Accordingly, a suitable alloy will provide a device that is capable of substantially 25 recovering its austenitic shape without significant plastic deformation, upon placement in the body.

The method of placement of the stent, and a stent system for practicing the method will now be described with reference to Figs. 6 and 7. The target site in the method is typically a neurovascular site, such as site 54, in the brain, which is accessible only via a tortuous vascular path 56, by which is meant a 30 vascular path containing a plurality of bends or turns which may be greater than 90° turns, and involving vessels which are less than about 8mm, and as small as 2-3 mm, in diameter.

Initially, a guide catheter 60 is placed at the target site according to known methods. Then the target site is accessed by a flexible guidewire (such as described in U.S. Patent No. 4,619,274) and a flexible catheter 64. Once the target site is reached, the catheter tube is pulled out, leaving the flexible 5 guidewire in place. The stent-delivery catheter 62, as seen in Fig. 6B, is advanced over the guidewire until the target site is reached.

The distal end of stent-delivery catheter 62 is shown in Fig. 7A, and includes a catheter 68 having an inner lumen having a diameter preferably between about 0.5 to 2 mm, e.g. 0.71 to 1.65 mm. A stent 70 constructed in 10 accordance with the invention is carried in its contracted state at the distal end of the catheter.

Once the stent-delivery catheter is in place, with its distal end at the target site, the guidewire is removed and replaced with a pusher wire 63 (as shown in Fig. 6B) having a distal-end stabilizer 65, which has a distal head surface 15 dimensioned to engage the proximal end of the stent. To deploy the stent, the pusher wire is advanced and pushed against the stent until the stent is pushed out of the catheter, as shown in Fig. 7B. Once released from the constraints of the catheter, the stent is free to self-expand to a diameter slightly greater than the diameter of the vascular site, thus locking the stent in place at the target site.

20 More specifically, the method of the invention includes navigating a guide wire to the target site, moving over the guide wire, a catheter having a lumen inner diameter of 0.5 to 2 mm and a distal end region in the lumen, and the stent of the invention, carried in its contracted state within the catheter's distal end region, until the catheter distal end is located at the target site. The guidewire is 25 then replaced with a pusher wire, which is advanced within the catheter to force the stent out of the catheter into the vascular site, where stent radial expansion to its expanded state is effective to lodge the stent at the target site.

The system of the invention used in carrying out the method includes a 30 guidewire that can be deployed at the target site, a catheter having a lumen inner diameter of 0.5 to 2 mm and a distal end region in the lumen, and adapted to be placed at the target site via such path, and the stent of the invention carried in its contracted state within the catheter's distal end region, where the catheter

and stent carried therein are adapted to be moved axially along the guide wire, for placing the catheter at the target site. A pusher wire is movable through the catheter for forcing the stent out of the catheter into the vascular site, where stent radial expansion to its expanded state is effective to lodge the stent at the 5 target site.

The stent and system employing the stent of the present invention can be used in the treatment of a variety of vascular lesions such as an aneurysm, fistula, occlusion, or narrowing and is particularly useful in treating targets located in tortuous and narrow vessels, for example in the neurovascular 10 system, or in certain sites within the coronary vascular system, or in sites within the peripheral vascular system such as superficial femoral, popliteal, or renal arteries.

From the foregoing, it can be appreciated how various objects and features of the invention are met.

15 The axial construction of the stent, composed of short tubular members joined by axial connections, and the ability of the joined members to flex radially, by distributed bending within the looped regions of the wire elements, allows the stent to be moved over high-angle, small-radius bends, with relatively little localized stress and metal fatigue.

20 The ability of the stent to be close-packed, in its contracted state, and have a smooth wave-like character in its expanded (and expanding) state, allows the stent to expand severalfold when deployed, with a minimum risk of metal fatigue due to concentrated stresses, or damage to the vessel wall, due to sharp points on the stent. In its expanded state, the stent provides good radial 25 strength, for holding the stent in place.

The stent has a low profile, which may be in the 2-4 mil range for stent thickness. Finally, the stent should provide an open-network skeleton that allows for delivery of additional agents, e.g., vaso-occlusive coils, through the stent into the underlying aneurysm cavity.

30 Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this

invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

IT IS CLAIMED:

1. A stent designed for catheter delivery to a target neurovascular site via a tortuous path in a contracted state, and deployment at the target site in an

5 expanded state, comprising

a plurality of expandable tubular members, each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks and having a wave shape such that the distance between adjacent sides of a wave in the stent's

10 expanded state, on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween, and

15 axial connectors joining adjacent tubular members,

wherein radial expansion of the stent from its contracted to expanded state is accommodated by movement of adjacent wave-segment peaks away from one another, without significant change in the axial dimension of the stent.

20 2. The stent of claim 1, wherein the wire elements are formed of a NiTi shape memory alloy, and said radial expansion is achieved by releasing the stent from such catheter.

25 3. The stent of claim 2, which has a stress-induced martensite phase at body temperature.

4. The stent of claim 2, which has an austenite phase transition temperature below body temperature.

30 5. The stent of claim 1, wherein the connectors connecting adjacent tubular members are attached to confronting peaks of the adjacent members, and the connectors are spaced from one another by intervening, unconnected confronting peaks.

6. The stent of claim 5, which can be carried in a distal end region of a catheter having a lumen inner diameter between about 0.5 and 2 mm, and adapted to be placed at the target site via a tortuous vascular path in the brain.

5 7. The stent of claim 1, wherein the stent in its contracted state has an inner diameter of between 0.5 and 2 mm, and the stent diameter in its expanded state is between 2-9 times that in its contracted state.

10 8. A system for treating a aneurysm or other vascular abnormality in a neurovascular target vessel having an inner diameter less than about 8 mm and accessible via a tortuous vascular path, comprising

15 a guide wire that can be deployed at the target site,
a catheter having a lumen inner diameter of 0.5 to 2 mm and a distal end region in the lumen, and adapted to be placed at the target site via such path,

20 the stent of claim 1 adapted to be carried in its contracted state within the catheter's distal end region, where the catheter and stent carried therein are adapted to be moved axially along the guide wire, for placing the catheter at the target site, and

25 a pusher wire movable through the catheter, for forcing the stent out of the catheter into the vascular site, where stent radial expansion to its expanded state is effective to lodge the stent at the target site.

9. The system of claim 8, wherein the stent wire elements are formed of a NiTi shape memory alloy, and said radial expansion is achieved by releasing the stent from such catheter.

10. The system of claim 9, wherein the stent is held in its contracted state in a stress-induced martensite state.

30 11. The system of claim 8, which further includes a stabilizer attached to the distal end of the pusher wire, engageable with the stent when forcing the same from the catheter.

12. The system of claim 8, wherein the stent in its contracted state has an inner diameter of between 0.5 and 2 mm, and a diameter in the expanded state of between 2-9 times that in the contracted state.

5 13. A method of treating an aneurysm or other vascular abnormality in a neurovascular target vessel having an inner diameter less than about 8 mm and accessible via a tortuous vascular path, comprising
10 navigating a guide wire to the target site,
 moving over the guide wire, a catheter having a lumen inner diameter of 0.5 to 2 mm and a distal end region in the lumen, and the stent of claim 1 carried in its contracted state within the catheter's distal end region, until the catheter distal end is located at the target site,
 replacing the guide wire with a pusher wire, and
 using the pusher wire to force the stent out of the catheter into the
15 vascular site, where stent radial expansion to its expanded state is effective to lodge the stent at the target site.

20 14. The method of claim 13, wherein the stent wire elements are formed of a NiTi shape memory alloy, and said radial expansion is achieved by releasing the stent from such catheter.

25 15. The method of claim 14, wherein the stent is held in its contracted state in a stress-induced martensite state.

30 16. The method of claim 13, wherein the pusher wire is equipped at its distal end with a stabilizer that is engageable with the stent when forcing the same from the catheter.

35 17. The method of claim 13, wherein the stent in its contracted state has an inner diameter of between 0.5 and 2 mm, and a diameter in the expanded state of between 2-9 times that in the contracted state.

ABSTRACT

A stent designed for catheter delivery to a target neurovascular site via a tortuous path, in a contracted state, and deployment at the target site, in an 5 expanded state, is disclosed. The stent includes a plurality of expandable tubular members, where member is composed of a continuous wire element forming a plurality of wave segments, and segment contains a pair of opposite looped peaks having a wave shape such that the distance between adjacent sides of a wave, on proceeding from a peak toward opposite peaks, increases 10 monotonically with an inflection point therebetween. The expandable tubular members are joined through adjacent peaks by axial connectors. Radial expansion of the stent from a contracted to expanded state is accommodated by movement of adjacent wave-segment peaks away from one another, without significant change in the axial dimension of the stent. Also disclosed are a 15 system incorporating the stent, and a method of treating a neurovascular abnormality.

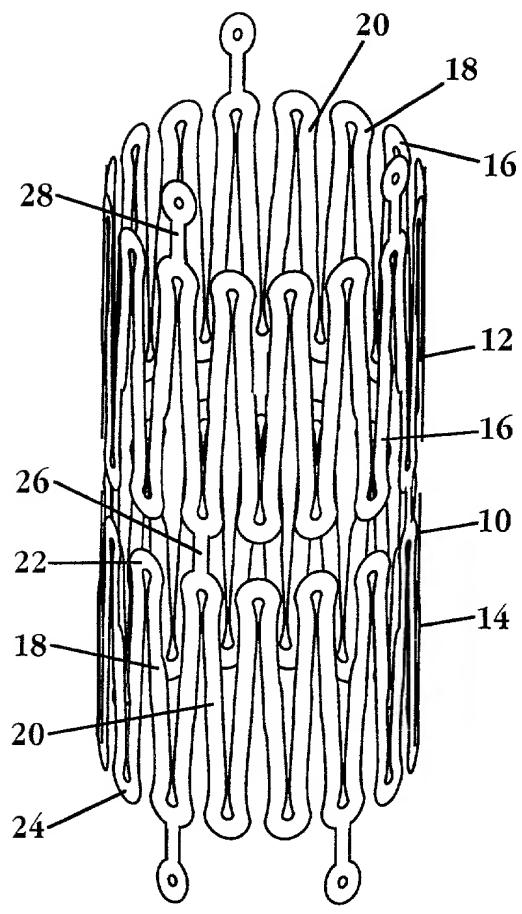


Fig. 1

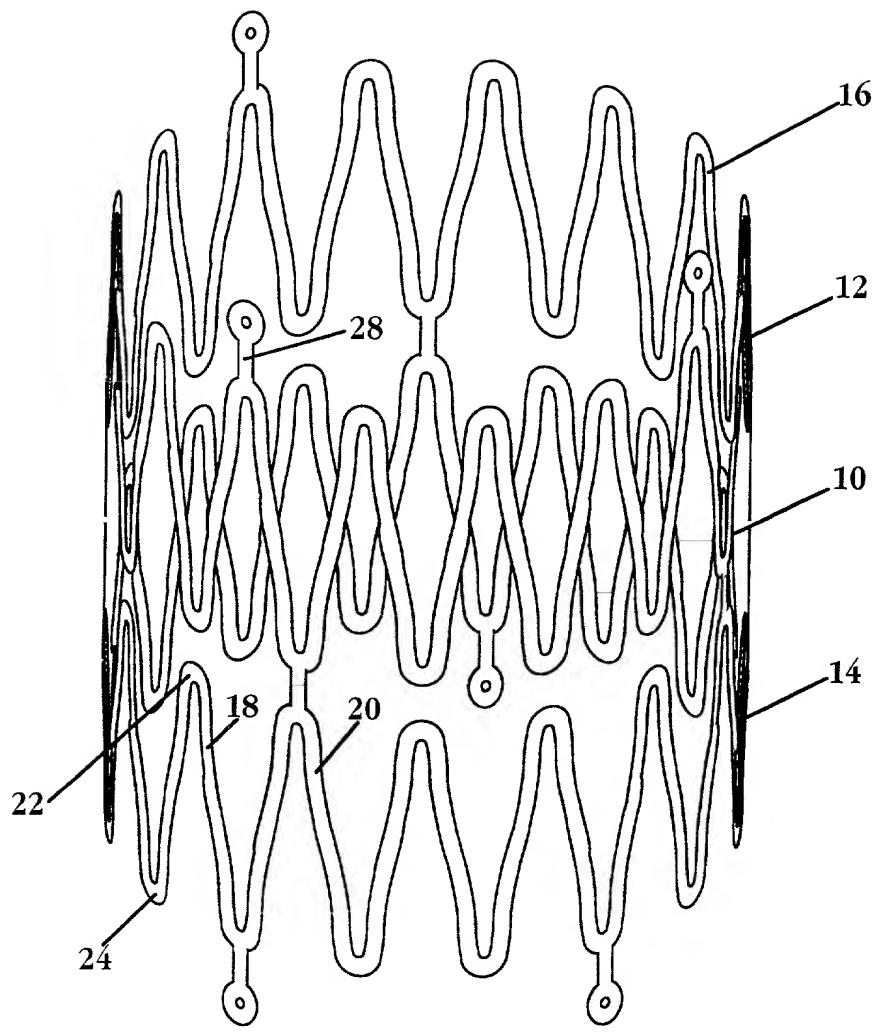


Fig. 2

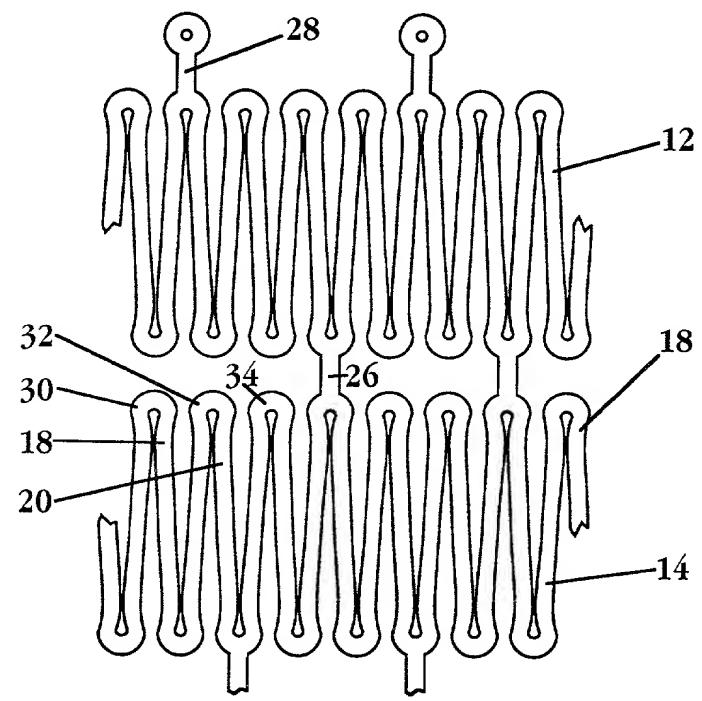


Fig. 3

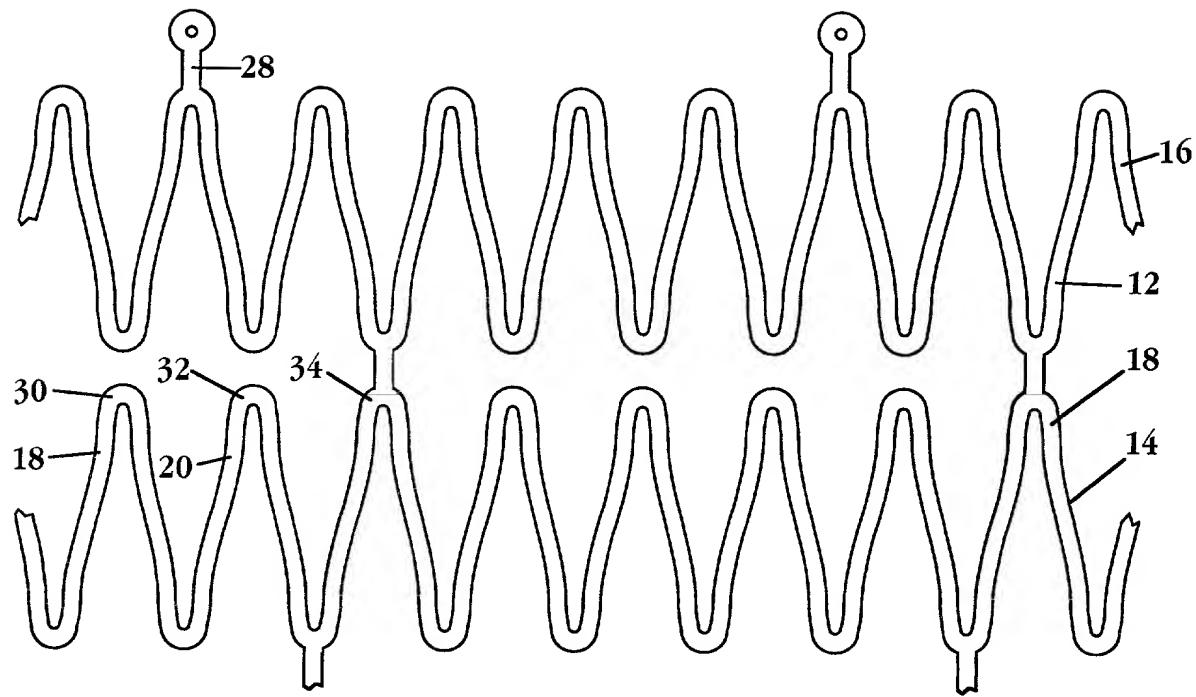


Fig. 4

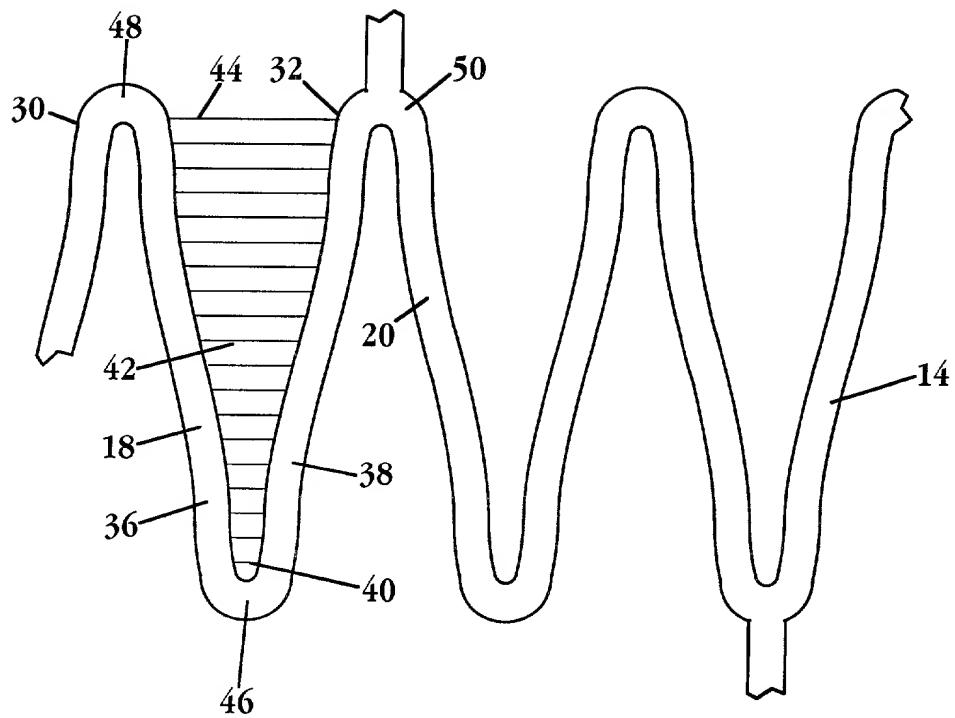


Fig. 5A

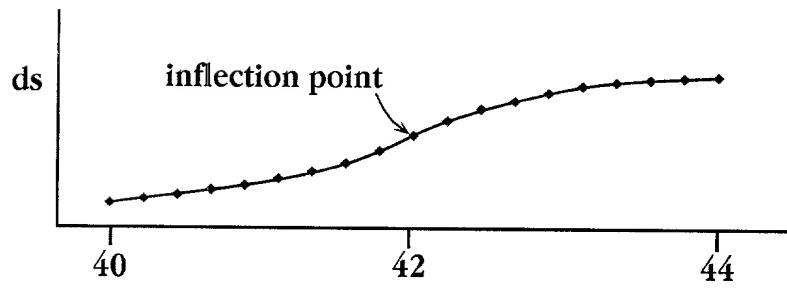


Fig. 5B

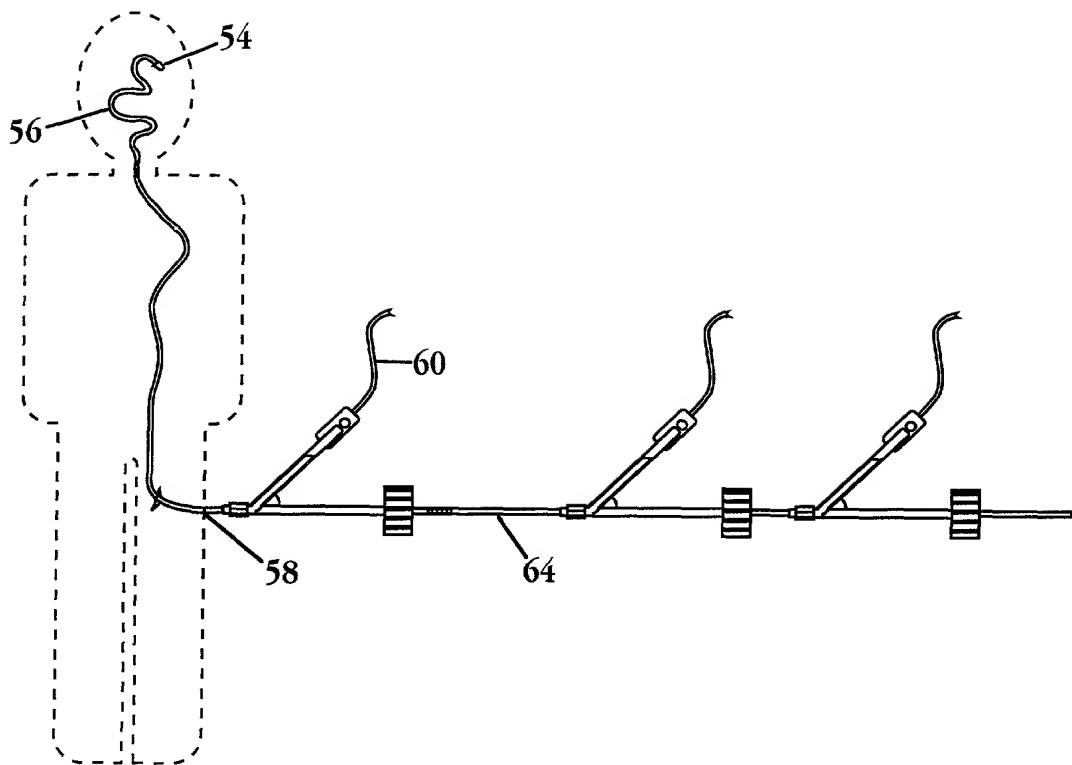


Fig. 6A

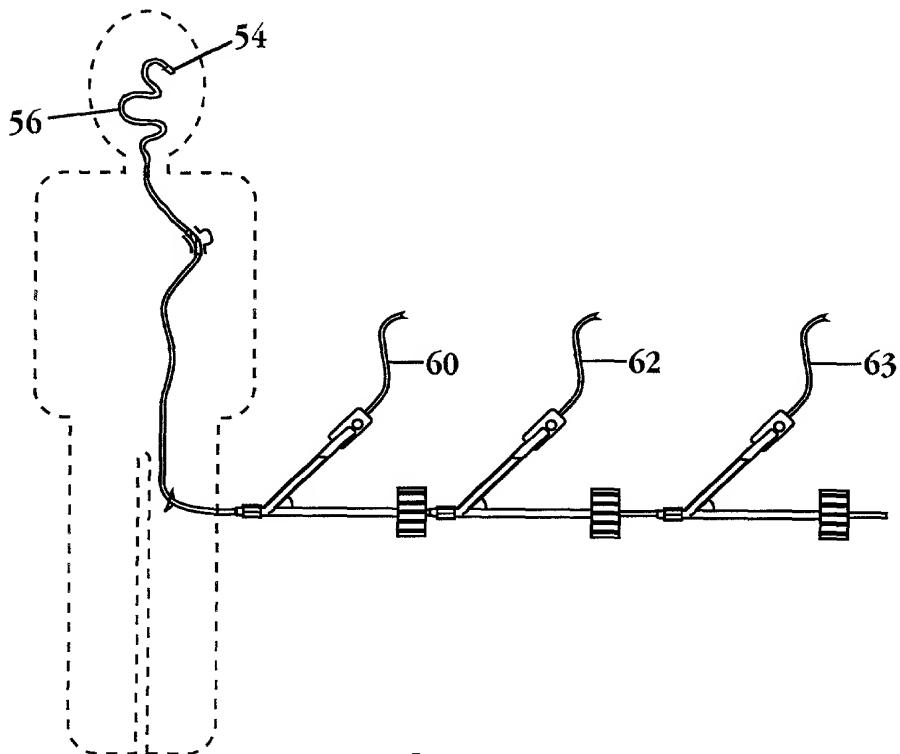


Fig. 6B

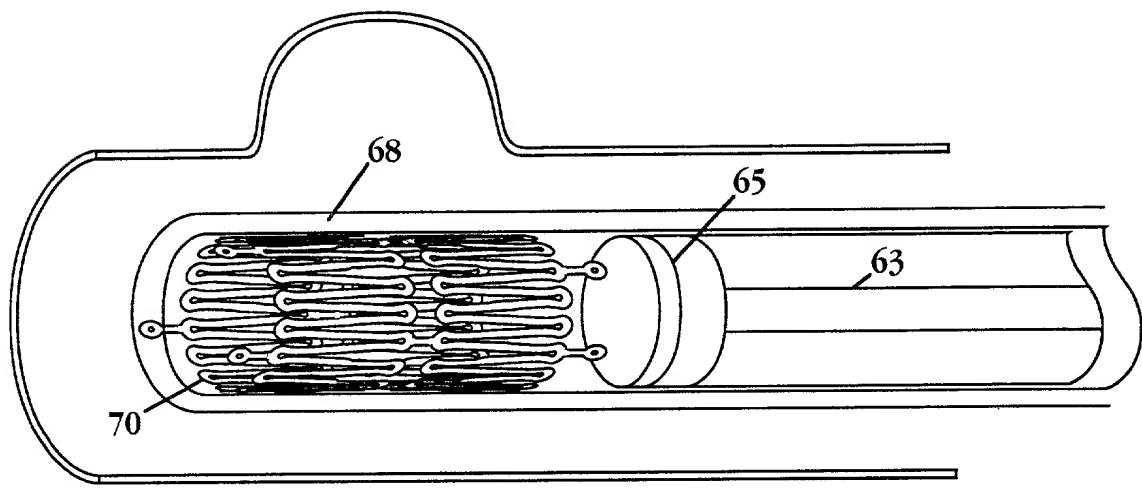


Fig. 7A

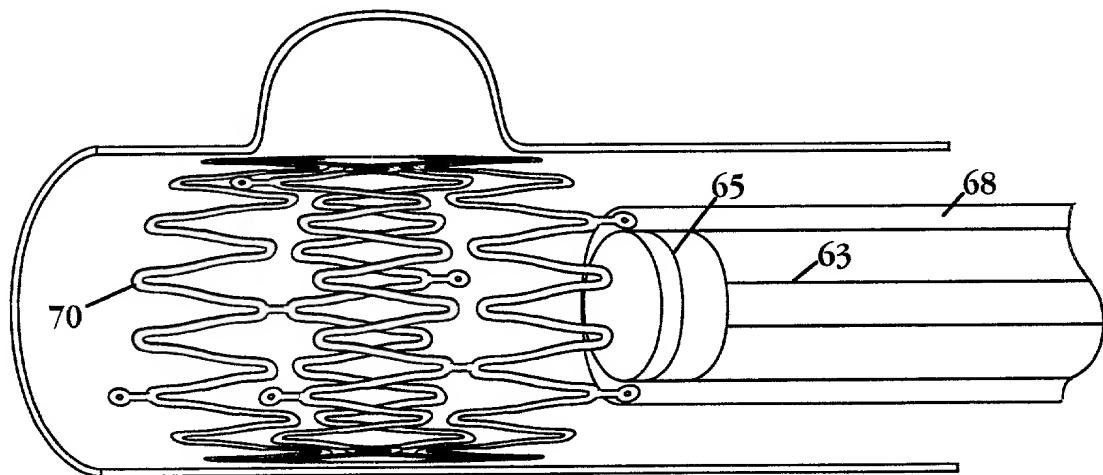


Fig. 7B

INVENTORSHIP DECLARATION BY SOLE INVENTOR

I HEREBY DECLARE THAT:

My residence, post office address, and citizenship are stated next to my name in PART A on hereof.

I believe I am the original, first, and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled

NEUROVASCULAR STENT AND METHOD

• the specification of which:

- is attached hereto.
- was filed on * as Application Serial No. *.

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate listed in PART B hereof and have also identified in PART B on hereof any foreign application for patent or inventor's certificate having a filing date before that of the application of which priority is claimed.

I hereby claim the benefit under Title 35, United States Code §119(e) and §120, of any United States application(s) listed in PART C hereof and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations §1.56 which occurred between the filing date of the prior application and any national or PCT international filing date of this application.

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Please direct all telephone calls to Peter J. Dehlinger at (650) 324-0880. Address all correspondence to:

**Iota Pi Law Group
P.O. Box 60850
Palo Alto, CA 94306-0850
Customer No. 22918**

INVENTORSHIP DECLARATION BY SOLE INVENTORPART A: INVENTOR INFORMATION AND SIGNATUREFull name of SOLE inventor: Patrick Rivelli, Jr.Citizenship: U.S.A. Post Office Address: 1430 Middlefield Road
Palo Alto, California 94301

Residence (if different): _____ (same) _____

Inventor's Signature: _____ Date: _____

PART B: CLAIM TO PRIORITY OF FOREIGN APPLICATION(S) UNDER 35 U.S.C. 119(a-d)

| Country | App. No. | Filing Date |
|---------|----------|-------------|
|---------|----------|-------------|

PART C: CLAIM TO PRIORITY OF U.S. PROVISIONAL AND NONPROVISIONAL
APPLICATION(S) UNDER 35 U.S.C. 119(e) AND 120

| Serial No. | Filing Date | Status |
|-------------------|-----------------|--|
| <u>60/241,101</u> | <u>10/16/00</u> | <input type="checkbox"/> Patented <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Abandoned |